

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

C. A. No. 13-cv-1729-SLR

**DECLARATION OF MARY W. BOURKE IN SUPPORT OF
PLAINTIFFS' MOTION FOR LEAVE TO FILE AN AMENDED COMPLAINT**

I, Mary W. Bourke, do hereby declare:

1. I am an attorney at the law firm of Womble Carlyle Sandridge & Rice, LLP, counsel for Plaintiff Takeda Pharmaceuticals U.S.A., Inc. in the above-captioned matter.

2. I submit this Declaration in Support of Plaintiffs' Motion for Leave to File an Amended Complaint.

3. Attached as Exhibit A is a true and correct copy of the webpage available at <http://rarediseases.info.nih.gov/gard/browse-by-first-letter/F>, as maintained by the National Institutes of Health, Office of Rare Diseases Research and as accessed on April 7, 2014.

4. Attached as Exhibit B is a true and correct copy of the webpage available at [http://www.orpha.net/consor/cgi-bin/Disease_Search.php?lng=EN&data_id=920&Disease_Disease_Search_diseaseGroup=Familial-Mediterranean-fever&Disease_Disease_Search_diseaseType=Pat&Disease\(s\)/group of diseases=Familial-Mediterranean-fever&title=Familial-Mediterranean-fever&search=Disease_Search_Simple](http://www.orpha.net/consor/cgi-bin/Disease_Search.php?lng=EN&data_id=920&Disease_Disease_Search_diseaseGroup=Familial-Mediterranean-fever&Disease_Disease_Search_diseaseType=Pat&Disease(s)/group of diseases=Familial-Mediterranean-fever&title=Familial-Mediterranean-fever&search=Disease_Search_Simple), as maintained by Orpha.net and last accessed on April 23, 2014.

5. Attached as Exhibit C is a true and correct copy of Plaintiff's First Set of Requests for Production to Amneal Pharmaceuticals, LLC as served on January 3, 2014.

6. Attached as Exhibit D is a true and correct copy of Plaintiff's First Set of Interrogatories to Amneal Pharmaceuticals, LLC as served on January 3, 2014.

7. Attached as Exhibit E is a true and correct copy of the Amended Complaint, D.I. 128, in *Novartis Pharmaceuticals Corp. v. Wockhardt USA LLC*, No. 13-cv-1028 (D.N.J.), as filed on March 15, 2013.

8. Attached as Exhibit F is a chart entitled "Summary of National Prescribing Data for Colchicine/Colcrys®," summarizing data from Encuity Research and IMS Health data.¹

9. Attached as Exhibit G is a true and correct copy of data from Encuity Research providing the total number of prescriptions for Gout and Familial Mediterranean Fever (indicated in yellow highlighting) for the month of June spanning from 2004 until 2013.

10. Attached as Exhibit H is a true and correct copy of data from the National Disease and Therapeutic Index providing the total number of colchicine prescriptions for Familial Mediterranean Fever (indicated in yellow highlighting) from 2008 through 2013.

11. Attached as Exhibit I is a true and correct copy of data from the National Disease and Therapeutic Index providing the total number of colchicine prescriptions for Gout (indicated in yellow highlighting) from 2008 through 2013.

¹ Takeda is submitting summary data in support of its Motion that is derived directly from the Encuity Research and IMS Health data. Takeda did not submit the entire Encuity Research or IMS Health prescribing data to the Court due to size and formatting concerns. If requested, Takeda will provide to the Court a native electronic version of the corresponding data on CD.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

This Declaration is executed this 13th day of May 2014.

/s/ Mary W. Bourke
Mary W. Bourke (#2356)

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on May 13, 2014, upon the following individuals via electronic mail:

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